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U.S. Patent and Trademark Office PTOL-37 (Rev. 1-04)

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## **DETAILED ACTION**

## **EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Dean Fanelli on March 23, 2005.

The application has been amended as follows:

- a) Claim 1, line 7:"section," (first occurrence of "section") has been replaced with
- -- section for introducing sample into the microstructure plate, --;
- b) Claim 1, line 7: -- microstructure -- has been inserted between "accepting" and "section";
- c) Claim 1, line 7: -- does not have an electrode and -- has been inserted between "section" (second occurrence or "section") and "is".
- d)Claim 1, line 17: "assembled" has been deleted; and
- e) Claim 11, line 1: "unit" has been replaced with -- plate --.

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## Allowable Subject Matter

2. Claims 1-50 are allowed.

3. The following is an examiner's statement of reasons for allowance:

a) The combination of limitations in Claim 1 requires (i) at least one sample accepting microstructure, which the examiner understands to be a microstructure distinct from the other microstructures recited in the claim, such as the at least one first electrode microstructure section or the at least one second electrode microstructure section. This understanding is reinforced by the limitations in claim 1 that the sample accepting microstructure section is for introducing sample into the microstructure plate and that the sample accepting microstructure does not have an electrode, and (ii) an electrode assembly, that is a structure, having at least one first electrode and at least one second electrode, wherein each first electrode microstructure section is in electrical contact with at least one first electrode, and wherein each second electrode microstructure section is in electrical contact with at least one second electrode.

In the Office action of May 17, 2004 ("the Office action") Ramsey '859 and Ramsey '229 were cited against claim 1 and several other claims that depend from claim 1. In neither Ramsey '859 nor Ramsey '229 is there a sample accepting microstructure distinct from an electrode microstructure. In the electrokinetic embodiments of Ramsey '859 the reservoirs 20, 22, 24, and 26, into which sample may be introduced, each contain an electrode. Thus, these reservoirs are electrode microstructures/potential sample accepting microstructures. See in Ramsey '859 col. 2:46-52; col. 2: 59-65; col. 3:45-50, and col. 5:26-32. Likewise, in Ramsey

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'229 reservoirs 30, 32, 34, and 36 each contain an electrode. See Figures 1 and 20 and col. 5: 20-24 in Ramsey '229 (note that reservoir "10" is not shown in the figures and clearly should be reservoir "30" instead). Sample can only be introduced into these reservoirs because cover plate 14 in Ramsey'859 and cover plates 28, 110, and 28' in Ramsey '229 cover all microstructures in the microplate except for a portion of each of these reservoirs. In contrast, Claim 1 requires at least one first electrode microstructure section with a first electrode and at least one second electrode microstructure section with a second electrode in addition to at least one sample accepting microstructure that does not have an electrode. Also, see page 10, lines 4-13 of the specification.

In the Office action Ullman and JP '616 were also cited against claim 1 and several other claims that depend from claim 1. Sample is introduced into reservoir 104 in Ullman. See col. 25:53-54. Reservoirs 102, 106, 108, and 116 are also disclosed as inlet reservoirs, although for materials other the sample. See col. 25:50-67. Ullman discloses in several passages performing electroseparation, electrophoresis, or some other electrokinetic technique. See col. 12:60 – col. 13:9; col. 22:10-26; col. 22:64 – col. 23:43. Ullman does not mention where the electrodes for performing the electrokinetic technique are to be located; however, with respect to the sample-accepting reservoir 104 Ullman states sample "is added by electrokinetic means to chamber 125." See col. 26:23-26. This would suggest to one with ordinary skill in the art at the time of the invention at least placing an electrode in the sample-accepting reservoir (or any other reservoir which could be used as a sample accepting reservoir), as an electrode is usually placed at each end of the path along which material is to be elecrokinetically transported. JP '616 in fact has an electrode in every reservoir in the disclosed microstructure device. See Figures 2 and

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4 and also see paragraph [0002] of the Detailed Description, which discloses that in the prior art a voltage is applied across the ends of a capillary electrophoresis channel. Thus, Ullman and JP '616 do not teach a sample accepting microstructure that does not have an electrode.

Swedberg and JP '616 were also cited against claim 1 and several other claims that depend from claim 1. In Swedberg sample is introduced into inlet port 18 inlet port 120 in the embodiment of Figures 1-6; inlet port 68 in the embodiment of Figures 7A and 7B; inlet port 68' in the embodiment of Figures 8A and 8B; inlet port 120 in the embodiment of Figures 10 and 11; inlet port unlabeled but shown at either end of channel 162 in substrate surface 158 in the embodiment of Figures 13 and 14; and inlet port 222 in the embodiment of Figure 15. See col. 16:8-14; col. 19:16-21; col. 20:61-67; col. 23:40-45; and col. 27:26-30. Swedberg discloses in several passages performing electroseparation, electrophoresis, or some other electrokinetic technique. See col. 11:45-61; col. 23:52-58; and col. 28:50-66. Although Swedberg discloses that an electrical potential may be applied across any portion of the column (col. 11:62-67), as determined in the Office action Swedberg does not an electrode assembly as recited in claim 1. Electrodes are disclosed for an electrochemical detector in the embodiment of Figure 5, but these electrodes are at the same location, so there is not more than one electrode microstructure as required by claim 1. See col. 17:44-48. These electrodes would include a working electrode and a reference electrode, which would be kept adjacent each other for more accurate measurement. Even, if it would have been obvious to provide more than one electrode microstructures with electrodes along the channel, the embodiment of Figure 5 does not have a capture microstructure. More particularly it does not have a capture microstucture between a first electrode microstructure having a first electrode and a second electrode microstructure having a second

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electrode. The embodiment in Figure 15 of Swedberg has four sample treatment regions (214, 216, 218, and 220); however, only one sample treatment region (214) is designated as a capture microstructure. See col. 27:65-67; col. 28:31-35; col. 28:51-53; col. 28:64-66; and col. 27:46-64. This capture microstructure uses a microparticle, membrane material, or chromatographic matrix for capturing the analtye. See col. 23-36. So, this capture microstructure is not between a first electrode microstructure having a first electrode and a second electrode microstructure having a second electrode. Even if one or more of the other sample treatment regions (216, 218, and 220) could be construed as potentially being capture microstructures there is no disclosure of having these capture microstructures between the first electrode and the second electrode of an electrode assembly, that is structure, having at least one first electrode and at least one second electrode, wherein each first electrode microstructure section is in electrical contact with at least one first electrode, and wherein each second electrode microstructure section is in electrical contact with at least one second electrode. JP '616 was cited in the Office action for an electrode assembly. However, in JP '616 there is an electrode in every port and claim 1 requires that the sample accepting microstucture does not have an electrode. Furthermore, in JP '616 the channel network is configured so that all of the ports are at one end of the microstucture plate. This is so the electrode assembly can be mated to the microstructure plate. See Figures 1, 2, and 4. Such an electrode assembly would not work with the channel arrangement in Figure 15 of Swedberg where the possible capture microstructures are at various locations along the length of the zigzaging channel and thus are not configured to have both ends of a capture microstructure at one end of the microstucture plate.

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b) Claims 2-50 depend directly or indirectly from allowable claim 1.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

## **Drawings**

- 4. The drawings were received on January 05, 2005. These drawings are accepted.
- 5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alex Noguerola Primary Examiner

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March 24, 2005